

Exhibit 4-2

WARNING LETTER CLOSE-OUT LETTER

Mr. John Doe, President
J.D. Laboratories, Inc.
Somewhere, USA

Dear Mr. Doe:

The Food and Drug Administration has completed an evaluation of (your/your firm's) corrective actions in response to our Warning Letter [insert WL # and Date]. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

Official [issuing district/office]

bcc: Establishment File
Home District of Corporate HQ (or of receiving firm if issued by a Center)
FOI Office for Posting (typically no redaction needed; electronic through
CMS)
CMS case file (electronic copy)